PILLSBURY WINTHROP SHAW PITTMAN LLP
BRUCE A. ERICSON (SBN 76342)
bruce.ericson@pillsburylaw.com
LEE BRAND (SBN 287110)
lee.brand@pillsburylaw.com
Four Embarcadero Center, 22nd Floor
San Francisco, CA 94111-5998
Telephone: 415.983.1000
Facsimile: 415.983.1200

WEI GROUP LLP
ERIC S. WEI (*pro hac vice* application forthcoming)
ewei@weillp.com
One World Trade Center, Suite 8500
New York, New York 10007-0103
Telephone: 212-248-0808
Facsimile: 212-248-0475

Attorneys for Defendant
K. Peony Yu, M.D.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO HEADQUARTERS

IN RE FIBROGEN, INC., SECURITIES LITIGATION

No. 3:21-cv-02623-EMC

CLASS ACTION

REPLY MEMORANDUM IN SUPPORT OF MOTION OF DEFENDANT K. PEONY YU, M.D. TO DISMISS CONSOLIDATED COMPLAINT

Date: April 28, 2022
Time: 1:30 p.m.
Courtroom: 5
Judge: Hon. Edward M. Chen

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

Cases

Statutes

Rules

I. INTRODUCTION

Plaintiffs' Omnibus Opposition, Dkt. 114 ("Opposition" or "Opp."), largely ignores the points made in Dr. Yu's moving papers. Instead, the Opposition lumps all Defendants together, never treating Dr. Yu as an individual, and repeats, mantra-like, the words "manipulation" and "falsification" – even though no well-pleaded facts show either.

Falsity: Dr. Yu played no role in the April 6, 2021 press release upon which Plaintiffs' theories of falsity (and scienter) rest. This press release is not her statement and did not implicate her – or anyone – in any deception. New management simply decided to change the labels on two analyses, labeling "primary" what had previously been labeled "sensitivity" and "sensitivity" what had previously been labeled "primary." That decision, and the market reaction to it, proves nothing about the objective or subjective truth of Dr. Yu's prior statements. FibroGen had presented both analyses to the FDA back in 2019, thus exploding the Opposition's brand new (and unpled) theory that Defendants "sought to deceive not only investors, but also the FDA." Opp. at 5 (emphasis in original). The change in labeling represents at most a difference of opinion – and an immaterial difference at that. The FDA, the AdCom, and FibroGen's new management all agree that (as the FDA put it): "The findings were qualitatively similar, regardless of the stratification factors." FDA Brief to the AdCom, Ex. VV at 47, Dkt. 111, at 823. ("Ex." refers to exhibits to the Kasner Declaration filed with the FibroGen Motion as Dkts. 110 and 111.)

Nor did FibroGen mislead the market. Before unblinding, FibroGen had told the market it would use both pre-specified and non-pre-specified analyses. After unblinding, FibroGen told the market that it did not yet have agreement with the FDA on the method of analyses but would be talking to the FDA about methods of analysis. After the pre-New Drug Application ("NDA") meeting with the FDA, FibroGen told the market that it had discussed methods that would include non-pre-specified analyses with the FDA and that the FDA had approved the methods. All this was disclosed repeatedly in SEC filings and earnings conference calls. However labeled, both sets of analyses were bona fide. The words "manipulation" and "falsification" have no application here.

Beyond the April 6 press release, Plaintiffs allege that Dr. Yu made 21 false and misleading statements, the earliest on December 20, 2018 (#1) and the latest on May 7, 2020 (#49) (CAC Appx.,

Dkt. 91-2), over a year before the end of the alleged class period (July 15, 2021) (CAC ¶ 2). Neither the CAC nor the Opposition plausibly alleges falsity (or scienter) based on these statements. The Opposition attempts to twist what Dr. Yu actually said through selective quotations (often of just a couple of words out of context) and ellipses (linking phrases that are pages apart in the transcript). Read in context, these are statements of opinion. The Opposition does not show them to be objectively or subjectively false; to allege a false opinion under *Omnicare*, it is Plaintiffs' burden to plead both. Many also are forward-looking statements protected by the PSLRA's safe harbor.

Scienter: Here, too, the Opposition – like the CAC – rests principally on conclusory and spurious allegations about the April 6 press release, which is simply not a statement, much less an admission, by Dr. Yu of anything. Plaintiffs' other scienter theories are equally untenable: the confidential witness does not specify what she says she heard Dr. Yu say, does not say whether it was false, and offers no basis for suggesting she knows Dr. Yu's state of mind; Dr. Yu's stock sales plummeted during the class period as compared to the period before, and all were made under 10b5–1 plans; and Dr. Yu's retirement came at a time that made sense – her work was complete and likely new management wanted a new team. Beyond that, it "simply 'does not make a whole lot of sense'" that Dr. Yu would have sought to deceive the market "knowing roxadustat would never be approved and the Company would 'face the inevitable fallout.'" FibroGen Mot. At 2 (quoting *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 415 (9th Cir. 2020)). The Opposition also never confronts the fact that roxadustat was approved for use by regulators around the globe, including Japan, China, Korea, and the European Union, among others. Plaintiffs offer no basis to infer Dr. Yu knew roxadustat would be rejected in the United States when it has been approved in so many other countries – seven of the ten largest pharmaceutical markets. FibroGen Reply, Dkt. 115, at 66:13.

In short, neither Plaintiffs' allegations of falsity nor their allegations of scienter against Dr. Yu meet the pleadings standards set by the PSLRA. The CAC therefore should be dismissed.

II. ARGUMENT

A. The Complaint Does Not Adequately Allege Falsity Against Dr. Yu

Dr. Yu played no role in the April 6 press release on which Plaintiffs' theory of this case rests and the press release does not contradict her prior statements. Plaintiffs also do not adequately

plead falsity as to her actual statements about the efficacy of roxadustat; the likelihood that it would avoid a "black box" label; the "non-inferiority margin" that the FDA might apply; or the drug's safety more broadly.

1. Dr. Yu had no role in the April 6 press release and it does not contradict her prior public statements

The Opposition dwells at length on FibroGen's April 6, 2021 press release and the reaction of securities analysts to it. *See, e.g.*, Opp. at 2, 9-13, 17-18, 28-31. But this was well after Dr. Yu stepped down as FibroGen's Chief Medical Officer in December 2020, and several weeks after she ceased being an employee in March 2021. Compl. ¶ 23. Neither the CAC nor the Opposition argues that Dr. Yu participated in or agreed with, much less controlled, the decision reflected in the press release. Nor do Plaintiffs argue that this statement is attributable to her. Because she did not speak in it, the press release is not something for which she is responsible under the securities laws. *Janus Cap. Grp., Inc. v. First Derivative Traders*, 564 U.S. 135, 142 (2011).

FibroGen's new management – not Dr. Yu – elected to change the labels "primary" and "sensitivity" on two sets of analyses used to evaluate the pooled roxadustat safety data. *See* 10-Q for Q2 2021, Ex. YY at 86, Dkt. 111, at 1347. There was nothing false or manipulative about this. When pooling data from six studies, FibroGen had to decide whether it would simply import the stratification factors used in the underlying separate studies (the "study-specific" or "pre-specified" stratification factors, which differed from study to study) or also use additional "common" stratification factors that would better facilitate analysis across six different studies. *See* FibroGen Mot. at 9-10; FibroGen Reply, Dkt. 115, at 3:7-4:24, 16:9-18:24. The FDA knew FibroGen used both "study-specific" and "common" but non-pre-specified factors, because the Pooling Statistical Analysis Plan FibroGen submitted to the FDA in August 2018 said so: "Study and other common stratification factors will also be included in the model." Ex. B at 137, Dkt. 110, at 215.

FibroGen likewise repeatedly told the investing public that it would use multiple methods of analysis, both pre-specified and not pre-specified. In May 2019, FibroGen said "we will present to regulatory authorities certain pre-specified and not pre-specified sub-populations and sub-group analyses (for example, incident dialysis), multiple secondary endpoints, and multiple analytical

methods (such as long term follow-up analyses), including adjusted and censored data, regulatory authorities may reject these analyses, methods, or even part of our trial design or certain data from our studies, the rationale for our pre-specified non-inferiority margins or other portions of our statistical analysis plans." *See* 10-Q for Q1 2019, Ex. L at 46, Dkt. 110, at 497.

In August 2019, after FibroGen held the pre-NDA meeting with the FDA, FibroGen said its forthcoming NDA would include "additional supportive analyses and sensitivity analyses as well as subgroup analyses …." *See* 10-Q for Q3 2019, Ex. S at 28, Dkt. 111, at 152); 10-K for 2019, Ex. W at 9, Dkt. 111, at 254 (same). And FibroGen's warnings to the investing public that the FDA might reject FibroGen's methods of statistical analysis and use other methods go back at least as far as 2017. *See* 10-K for 2017, Ex. A at 85-86, Dkt. 110, at 36-37.

Making the point even more concrete, in May 2019, when it unblinded the pooled data, FibroGen told the public that issues had arisen in the non-dialysis ("NDD") studies because the data showed that placebo patients became sicker and dropped out faster than roxadustat patients, thus skewing the results (e.g., if a patient on placebo dropped out of the study due to worsening health conditions, that patient's later MACE event would not be included in the study, thus creating a misleading picture). FibroGen explained this to the public when it unblinded the pooled data. *See* Transcript of Earnings Conference Call, May 9, 2019, Ex. J at 5-6, Dkt. 110, at 440-41. FibroGen said this issue would be discussed with the FDA at the pre-NDA meeting but as of unblinding "we do not have a specific agreement with FDA on methods of analysis." *Id.* at 440-41, 452.

From August through November 2019, *after* the pre-NDA meeting, FibroGen told the public that the FDA had agreed to using a primary NDD analysis of "Intent to Treat," so that the fate of patients who dropped out of the study would be included. *See* 10-Q for Q3 2019, Ex. S at 28, Dkt. 111, at 152. FibroGen also told the public that it and the FDA had agreed, at the meeting – four months after the pooled data unblinding – to endpoints and methods of analysis. *See* Earnings Conference Call, Aug. 8, 2019, RJN Ex. N at 5, 9, Dkt. 111, at 39, 43; Earning Conference Call, Nov. 11, 2019, Ex. R at 12, 14-15, Dkt. 111, at 137, 139-40. These disclosures rebut the Opposition's argument that FibroGen misled the public and the FDA as to the use of analyses added post-unblinding.

In the end, the change in labeling made no difference to anybody. The FDA stated: "The MACE meta-analysis included pre-specified, trial-specific stratification factors. The applicant also provided results using common stratification factors defined post hoc. The findings were qualitatively similar, regardless of the stratification factors." FDA Brief to AdCom, Ex. VV at 47, Dkt. 111, at 823. FibroGen's new management also ultimately thought it did not matter. Following an internal review, the same subsequent management that issued the April 6 press release issued the following "major findings":

> • The underlying data used for cardiovascular safety analyses are accurate, with no data integrity issues with the data used to generate such analyses.
>
> • In its NDA, the Company calculated accurately and described both sets of analyses, including the statistical methodologies and stratification factors utilized. The statistical analyses using post-hoc stratification factors were designated as "primary" analysis, and the statistical analyses using pre-specified stratification factors as a "sensitivity" analysis. . . .
>
> • Those responsible for the statistical analyses believed that it was a reasonable and valid way to analyze and present the data.

10-Q for Q2 2021, Ex. YY at 86, Dkt. 111, at 1347. In short, no data was falsified, nothing was hidden from the FDA, and no one deceived the FDA or the market. Thus, the April 6, 2021 press release does not reflect Dr. Yu (or anyone else) "admitting that the Phase 3 safety results . . . were not the drug's true data derived from prespecified analyses agreed upon with the FDA, but were falsified data that Defendants had intentionally manipulated '*post hoc*'" or "that they had not only presented false data to investors, but also to the FDA." Opp. at 2 (emphasis in original).

All the data and analyses presented in FibroGen's April 6, 2021 press release, and discussed with the AdCom, were presented to the FDA in the NDA in December 2019. The data and analyses presented to the American Society of Nephrologists in November 2019 (and to the public via a Form 8-K) are those then deemed by FibroGen – and still believed by Dr. Yu – to be appropriate primary analyses and consistent with the agreement reached with the FDA at the pre-NDA meeting. Ex. R at 15, Dkt. 111, at 140.

As set forth in Dr. Yu's motion, and uncontested by the Opposition, the case law is clear that the disclosure of FibroGen's then primary analyses did not obligate FibroGen to disclose sensitivity analyses. *See* Yu Mot. at 10; *Corban v. Sarepta Therapeutics, Inc.*, 868 F.3d 31, 40 (1st Cir. 2017); *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1061 (9th Cir. 2014) ("Rule

10b–5 prohibits 'only misleading and untrue statements, not statements that are incomplete'" and "[w]e have expressly declined to require a rule of completeness for securities disclosures" (quoting *Brody v. Transitional Hosps. Corp.*, 280 F.3d 997, 1006 (9th Cir. 2002)); *accord, Weston Family Partnership LLLP v. Twitter, Inc.*, -- F.4th --, No. 20-17465, 2022 WL 853252, at *2, *5 (9th Cir. Mar. 23, 2022) (the securities laws "do not require real-time business updates or complete disclosure of all material information whenever a company speaks on a particular topic;" rather, "a company can speak selectively about its business so long as its statements do not paint a misleading picture," and statements are "not false or misleading [if] they were qualified and factually true").

After Dr. Yu left FibroGen, new management decided to change what was labeled as "primary" and "sensitivity" analyses, and at that point disclosed what until then had been labeled one of several sensitivity analyses. New management had the right to do so, but its decision to do so in 2021 did not render false anything that Dr. Yu had said in 2019 and 2020 based on the analysis deemed primary on her watch, a method of analysis discussed with and agreed to by the FDA.

2. Dr. Yu said nothing false about efficacy (Statements ##1, 6, 44, 46-49)

Roxadustat is efficacious—that is, it works. The FDA, in its brief to the AdCom, said roxadustat's "efficacy is not in question" as "[a]ll studies … demonstrated efficacy." Ex. VV at 7, Dkt. 111, at 783. And the AdCom "believe[d] that the applicant has provided substantial evidence of efficacy for the indication they are seeking." Ex. XX at 141, Dkt. 111, at 1140.

The Opposition's efficacy argument rests on a rhetorical sleight of hand: conflating efficacy with safety. Opp. at 23-24. The two are medically and legally distinct concepts. *See, e.g.*, 21 U.S.C. § 355(b)(1)(A)(i) (requiring new drug applications to include "full reports of investigations which have been made to show whether such drug is safe for use ***and*** whether such drug is effective in use" (emphasis added)); *see also In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 523 (S.D.N.Y. 2015) (discussing FDA advisory panel votes of 12 to 6 that company had provided substantial evidence of drug's efficacy and of 17 to 0 that safety concerns about drug should not preclude FDA approval for certain patients), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016). Apart from this, the Opposition makes no serious argument that Dr. Yu ever said anything false about efficacy.

Statements #1 and #6, from late 2018 and early 2019, allege that Dr. Yu expressed the belief that study results demonstrated roxadustat's efficacy in treating anemia. *See also* Ex. E at 4 (#1), Dkt. 110, at 346; Ex. G at 6 (#6), Dkt. 110, at 364. Such "publicly stated interpretations of the results of various clinical studies . . . are essentially no different than opinions" and cannot state a claim for fraud unless Plaintiffs "allege with particularity provable facts to demonstrate that the statement of opinion is both objectively and subjectively false." *In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 567 (S.D.N.Y. 2011) (internal quotation marks omitted); *see also Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 176 (2015) (a sincerely held opinion statement is not actionable even if the "stated opinion ultimately proves incorrect"); *Rubke v. Capitol Bancorp*, 551 F.3d 1156, 1162 (9th Cir. 2009). The CAC does not allege facts suggesting subjective falsity – that is, that Dr. Yu did not believe what she was saying. Plaintiffs' only argument is that Defendants could not have believed what they said about efficacy because they supposedly manipulated the safety analyses. But as already shown above, roxadustat's efficacy is not in doubt, and there was no manipulation of safety analyses. Plaintiffs' argument is a falsehood ("manipulation") piled upon a fallacy (efficacy).

Statements #44 and ##46-49 allege that Dr. Yu expressed confidence about roxadustat's efficacy at earnings conference calls on March 2, 2020 (#44; *see* Ex. V at 6, Dkt. 111, at 232) and May 7, 2020 (##46-49; *see* Ex. X, Dkt. 111, at 348-49, 355). The statements express the belief that study results demonstrated roxadustat's efficacy in treating anemia. These are opinions about study results – accurate even in hindsight. Nothing suggests Dr. Yu did not believe what she said.

Doubling down on its conflation of efficacy with safety, the Opposition argues that roxadustat's efficacy was in fact highly questionable in the eyes of the FDA and rendered moot by safety issues that Defendants allegedly never disclosed. Opp. 24. As stated above, both the FDA and the AdCom found that roxadustat is efficacious, that its "efficacy is not in question," that "[a]ll studies … demonstrated efficacy," and that there is "substantial evidence of efficacy." Ex. VV at 7, Dkt. 111, at 783; Ex. XX at 141, Dkt. 111, at 1140..

For these reasons, the CAC does not adequately allege that Dr. Yu's statements about the efficacy of roxadustat were objectively or subjectively false.

3. Dr. Yu said nothing false about the possibility of a "black box" label (Statements ##21, 44, 49)

The Opposition's "black box" argument is a red herring. Over and over and over again, FibroGen told the market that labeling was beyond FibroGen's control and in the hands of the FDA, that roxadustat, if approved, might end up with a black box label and that, even if it avoided a black box, it might end up with a label that might "contain other warnings that limit the market opportunity for roxadustat." *E.g.*, 10-K for 2017, RJN Ex. A at 91, Dkt. 110, at 42; 10-K for 2018, Ex. H at 69, id. at 392; 10-Q for Q2 2019, Ex. O at 51, Dkt. 111, at 70; 10-Q for Q3 2019, Ex. S at 57, id. at 170; 10-K for 2019, Ex. W at 54, id. at 299; 10-Q for Q2 2020, Ex. DD at 52, id. at 443. Rather than meaningfully respond, the Opposition relies on cherrypicked excerpts that misrepresent the documents from which Plaintiffs quote.

For example, CAC ¶ 5 suggests that Dr. Yu said roxadustat would avoid a "black box" label. But the document referred to (a press release, Ex. E, Dkt. 110, at 342-49), Dr. Yu says nothing at all about labels.

For Statement #21, the Opposition quotes only the underlined portions of the transcript of the May 9, 2019 conference call, omitting the portion where Dr. Yu says that the FDA, not FibroGen, will determine the label:

> Now when -- now what FDA puts on the label is something that they -- that we may not have much control over, except that we have developed a package that we'll target a certain label. And so we -- FDA has advised us that the evaluation of efficacy, primary efficacy, will be based on individual studies, and we have checked that box. And the evaluation of safety is FDA may -- will look at various aspects of safety. And based on what we have seen, we are pretty comfortable with safety. This adjudicated composite safety endpoint was something that we have discussed with the FDA. And at this time, we are quite happy with the result.

Ex. J at 22, Dkt. 110, at 457 (language quoted in Opp. at 21 n.13 underlined).

For Statement #44, the Opposition quotes only the underlined portions of the transcript of a March 2, 2020 conference call, omitting the words where Dr. Yu, in response to a question about competitor data, outlined the rationale for the placebo-controlled study design, and expressed nothing more than "hope and confidence":

> So without seeing competitors' data is difficult to compare who has better data. And we know that in -- when you conduct a clinical trial, especially in safety outcome trial, one could expect a variety of outcome. And we are -- we have demonstrated a very favorable benefit

> and risk ratio. Now, however, I could comment on the Phase III study design, that we have designed a program to demonstrate safety in comparison to placebo and with the hope and confidence of gaining clean safety label for non-dialysis.

Ex. V at 10-11, Dkt. 111, at 236-37 (language quoted in Opp. at 21 n.13 underlined).

For Statement #49, the Opposition quotes only the underlined portions of the transcript of a May 7, 2020 conference call where Dr. Yu, again responding to a question about competitor data, said:

> And so in conclusion, roxadustat, excellent cardiovascular safety profile, coupled with the statistically significant and clinically meaningful, higher hemoglobin efficacy results and lower transfusion rate relative to epoetin alfa, together makes roxadustat potentially a better treatment option for dialysis-dependent patients. We like the hand that we have and expect the product label to reflect the results of clinical trials on our compound.

Ex. X at 10-11, Dkt. 111, at 348-49 (language quoted in Opp. at 21 n.13 underlined). Moreover, when a direct question about a "black box" label was raised later on that same call, FibroGen's CEO responded: "the data that we have, we do not believe warrants a black box, but this is a decision for the regulators." *Id*. at 16-17, Dkt. 111, at 354-55. All of these statements by Dr. Yu were forward-looking expressions of opinion, accompanied by cautionary remarks, hence not actionable. *See* FibroGen Reply, Dkt. 115, at 19:4-20:24

Nor does the CAC plausibly allege that Dr. Yu did not believe what she said. Plaintiffs say it was false for Dr. Yu to suggest "that the fate of Roxadustat's label was 'in the hands of the FDA'" Opp. at 22 (quoting Yu Mot. at 1), because "Defendants knew, but failed to disclose, that they had manipulated all nine safety analyses post hoc . . . ." *Id*. But this is simply a retread of Plaintiffs' misreading of the April 6 press release and fails for the reasons discussed above—*i.e.*, FibroGen told the FDA and the market that it would employ both pre-specified and non-pre-specified analyses, and post-unblinding the FDA agreed. For these reasons, the CAC does not adequately allege that Dr. Yu's statements about the likelihood of avoiding a "black box" label were false.

4. Dr. Yu said nothing false about the "non-inferiority margin" that the FDA might apply (Statement #20)

As explained in Dr. Yu's moving papers (Yu Mot. at 5-6), the only "non-inferiority margin" statement attributed to her was her May 9, 2019 description of a margin of 1.3 as a "conventionally accepted measure," "a commonly accepted statistical standard for noninferiority," and as consistent

with "conventional standards of noninferiority, which is widely published for assessment of CKD anemia and have previously been used by U.S. regulator for assessment of cardiovascular safety in similar types of composite endpoints." Ex. J at 8, 13, 20, Dkt. 110, at 443, 448, 455.

The Opposition argues that these statements "were materially false and misleading" because "the FDA had emphatically rejected 1.3 as invalid and had stated all along that its goal was an upper bound of 1.25." Opp. at 20 (emphasis in original). But this is not what the FDA said in its brief to the AdCom. It said: "The FDA did not agree prospectively on a risk margin and did not agree on the interpretation of the results using strictly a non-inferiority hypothesis testing approach." FDA's Brief, Ex. VV at 47, Dkt. 111, at 823. The discussion between the two AdCom members cited in the Opposition merely shows that "1.3 is reasonable. It was used in the diabetes guidance" (Dr. Ellis Unger) and "there was not an agreement on 1.3, and I agree with everything that Dr. Unger has said regarding it's somewhat arbitrary" (Dr. Ann Farrell). Ex. XX at 195-96, Dkt. 111, at 1194-95. In short, the FDA statements upon which Plaintiffs rely demonstrate that the FDA ***agreed*** with Dr. Yu that 1.3 was a "reasonable" non-inferiority margin and ***confirm*** that the FDA had not set any definitive margin as of May 2019 when Dr. Yu spoke on this subject. *See also* 10-Q for Q2 2019, Ex. O at 43-44, Dkt. 111, at 62-63 (stating that "the ultimate approval criteria (which may include non-inferiority margins and statistical analyses methods), indications, patient populations, and ultimate benefit-risk analysis used by regulatory authorities in their approval processes" are among factors beyond FibroGen's control).

For these reasons, the CAC does not adequately allege that Dr. Yu's statements describing 1.3 as a "commonly accepted" and "conventional" non-inferiority margin were false.

5. Dr. Yu said nothing false about safety (Statements ##7, 10, 13, 16-18, 20, 23, 26-27, 34-35, 44, 46-49)

Dr. Yu's statements about the safety of roxadustat all were either nonactionable expressions of opinion interpreting study data, nonactionable expressions of corporate optimism, or both. *See* Statements ## 7, 10, 13, 16-18, 20, 23, 26-27, 34-35, 44, 46-49; Yu Mot. at 6-10; *In re Sanofi-Aventis Sec. Litig.,* 774 F. Supp. 2d 549, 567 (S.D.N.Y. 2011)*; In re Copper Mountain Sec. Litig.*, 311 F. Supp. 2d 857, 868, 869 (N.D. Cal. 2004); *Kovtun v. VIVUS, Inc.*, No. 10-CV-4957-PJH,

2012 WL 4477647, at *11 (N.D. Cal. Sept. 27, 2012), *aff'd sub nom. Ingram v. VIVUS, Inc.*, 591 F. App'x 592 (9th Cir. 2015); *In re Splash Tech. Holdings, Inc. Sec. Litig.*, 160 F. Supp. 2d 1059, 1077 (N.D. Cal. 2001).

The Opposition focuses on Dr. Yu's statements during a November 11, 2019 investor call. Opp. at 8 (Statements ##34-35). Once again, Plaintiffs take her words out of context—presenting Dr. Yu's answers to different questions found pages apart in the transcript as a single statement—to misleadingly suggest certainty and guaranteed outcomes rather than her actual forward-looking optimism accompanied by appropriate cautionary remarks. In reality, the transcript reads in relevant part as follows (again, Plaintiffs quote only the underlined words):

> [Analyst:] I would just like to understand, since there seems to be some investor concern about FDA agreements and FDA sign-off [from] statistical [stance], how your general impression was of your meeting with the FDA? And why you feel confident about statistical protocols and their signing off of what you have from statistics and why you feel good about that? . . .
>
> [Dr. Yu:] . . . First of all, I wanted to share that we have been in dialogue with the FDA in the past 6 years. And there has been a very good understanding about what the Phase III required study would look like and including the size of the study, how to power it [for example] what's the primary endpoint and we agree on time to meet at [sic: MACE as] the primary endpoint, and that's how we power for the non-dialysis and the dialysis. And we've also had a very productive dialogue with the FDA on the analysis of cardiovascular safety as well as what the efficacy requirement needs to be for this submission. And the most recent conversation with the FDA was at the end of July. And we had sent it to the FDA, a fairly comprehensive briefing package and had a very productive meeting. And walking out of it, we felt that we had all the guidance from the FDA we needed to put together a winning submission. And that is about to be out the door this quarter.
>
> [Analyst:] So you feel no issue or no real concern about the hazard ratios and the [upper bounds] and all the things that people are talking about? You look at diabetes programs and things like that, there's – you're well within that. So you don't feel any concern about that?
>
> [Dr. Yu:] No, we have no concern about that. And Mike, as you know, that our regulatory assessment is not based on 1 criterion. But instead, it is based on totality of evidence such as efficacy, safety, what is the medical need. And so based on our discussions and the historical precedents in this therapeutic area and the various conversations we've had with the agency, we are very comfortable with our data where it is now.

Ex. R at 12, Dkt. 111, at 137 (language quoted in Opp. at 8 underlined). Several questions later, a different analyst inquired about when Fibrogen would talk to the FDA about its "statistical analysis plan," and in this context, Dr. Yu stated:

> Okay. So the answer to that question is that we had already talked with the FDA about analytical plan, and we had made the agreement on the analysis plan. The results that we have presented in the high-impact clinical session at the ASN, and the numbers I had just presented were based on the agreed analysis plan that we have made with the FDA.

Ex. R at 14-15, Dkt. 111, at 139-40 (language quoted in Opp. at 8 underlined).

Plaintiffs have no basis for alleging that Dr. Yu knew or believed any of this was false. Plaintiffs' theory again reduces to the same allegation that such falsity was "admitted" in the April 6 press release issued by "Defendants." *See* Opp. at 18, 24. No matter how many times Plaintiffs underline the word "manipulated," the decision in April 2021 of FibroGen's new management to change the labeling of the pooled safety analyses does not render Dr. Yu's statement in November 2019 false or constitute data manipulation – after all, *both* sets of analyses had been agreed with the FDA at the pre-NDA meeting in July 2019 and presented to the FDA in the NDA in December 2019. Plaintiffs' argument fails because "Plaintiffs cannot premise a fraud claim upon a mere disagreement with how defendants chose to interpret the results of the clinical trial." *In re MELA Sciences, Inc. Sec. Litig.*, No. 10-CV-8774-VB, 2012 WL 4466604, at *13 (S.D.N.Y. Sept. 19, 2012).

B. The Complaint Does Not Adequately Allege Scienter Against Dr. Yu

Considered individually or holistically, none of the allegations in the CAC that Dr. Yu acted with scienter satisfies the standard set forth in *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). Nothing in the Opposition alters that conclusion.

The April 6, 2021 press release: As with falsity, Plaintiffs' primary scienter arguments revolve around this press release. Opp. 28-31. But new management wrote the press release and made the decision to change which analysis was labeled "primary" and which was labeled "sensitivity." The press release is not an admission or even a statement by Dr. Yu. It says nothing about her state of mind in April 2021, when she did not speak, much less in May through November 2019, when she did speak. New management – which did speak in April 2021 – investigated how the primary and sensitivity analyses had originally been selected and presented to the FDA, concluding that the NDA was "calculated accurately and described both sets of analyses, including the statistical methodologies and stratification factors utilized" and that those "responsible for the statistical analyses believed that it was a reasonable and valid way to analyze and present the data." Ex. YY at 86, Dkt. 111, at 1347. Simply put, Plaintiffs do not allege that there was any disagreement about how to present the pooled safety data in 2019 – when Dr. Yu's challenged statements were actually made – or that Dr. Yu or anyone else believed at that time that it was

necessary to disclose the then-labeled sensitivity analyses to avoid misleading the market. New management's decision years later to change the labels does not support any inference that Dr. Yu purposefully chose to present data in a misleading fashion in 2019. Also, as discussed above, neither the FDA nor the AdCom found any significant difference in the two analyses.

Confidential witnesses: Plaintiffs argue that the CAC "does not lack allegations of 'direct interaction'" because "it alleges CW 3, a Global Vice President at FibroGen partner AstraZeneca, attended 'boardroom meetings' where 'Defendant Yu presented data from FibroGen slide decks.'" Opp. at 31 n.23 (quoting FibroGen Mot. at 22 and CAC ¶¶ 124, 251). But as set forth in Dr. Yu's motion and unaddressed in the Opposition, speculation by this non-scientist who merely sat in the audience at an unidentified meeting and heard unspecified statements raises no inference of scienter. Yu Mot. at 12; *City of Sunrise Firefighters' Pension Fund v. Oracle Corp.*, No. 18-CV-04844-BLF, 2019 WL 6877195, at 19 (N.D. Cal. Dec. 17, 2019).

Compensation: Plaintiffs first point to "stock and option awards directly tied to completing the manipulated Roxadustat MACE safety analysis and the submission of the misleading Roxadustat NDA to the FDA." Opp. at 32. But because these awards were tied to ***completing*** the safety study and ***submitting*** it of the NDA – as opposed to being triggered by achieving certain results or gaining FDA's approval – they provide no incentive to fudge the data in hopes of gaining FDA approval.

Plaintiffs' allegations about stock sales rebut an inference of fraudulent intent: Dr. Yu sold far less stock *during* the 31-month class period (sales totaling $39,456) than in the 31 months *before* the class period ($219,187) – and all under Rule 10b5–1 plans. *See* Kasner Decl., Dkt. 110, ¶¶ 55, 60-69, App'x A, Ex. AAA; *Lipton v. Pathogenesis*, 284 F.3d 1027, 1038 (9th Cir. 2002); *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1067 (9th Cir. 2008); *City of Royal Oak Ret. Sys. v. Juniper Networks, Inc.*, 880 F. Supp. 2d 1045, 1069 (N.D. Cal. 2012).

Resignation: Plaintiffs argue that "Yu's abrupt resignation . . . is highly suspicious and indicative of scienter." Opp. at 33. But in her motion, Dr. Yu explained that she departed at a logical time: "just ahead of the anticipated FDA approval date for roxadustat" when the "clinical trials she had led for years had ended, approval was anticipated, and a new CEO had taken over and likely wanted his own team." Yu Mot. 13. She left with praise from the new CEO, she was offered

and accepted an ongoing role as an advisor and then a consultant, and an internal investigation exculpated her of any inference of bad faith or wrongdoing. Yu Mot. at 13-14. All this rebuts any inference of scienter. *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 989 (9th Cir. 2009), *as amended* (Feb. 10, 2009); *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1062-63 (9th Cir. 2014).

The Opposition offers this tortured bit of logic: "Yu's brief stint as a consultant does not negate scienter" because any "'innocent inference is undermined by allegations that' FibroGen 'continued to struggle with transparency after the initial resignation[].'" Opp. at 33 n.27 (quoting *In re WageWorks Inc., Sec. Litig.*, No. 18-CV-01523-JSW, 2020 WL 2896547, at *7 (N.D. Cal. June 1, 2020)). But *WageWorks* involved a CEO who resigned to serve as Executive Chairman following internal controls issues but was then forced to resign from that role as well on the recommendation of the company's auditors, who could no longer rely on his representations. In that very different context, there was no "innocent inference" based on the fact that he "had initially stayed on as Executive Chairman." 2020 WL 2896547, at *7 n.5. There is nothing like that here.

Theories of scienter nearly identical to Plaintiffs' theory about Dr. Yu have "already been rejected as nonsensical" by the Ninth Circuit and this Court. FibroGen Mot. at 21. As the Ninth Circuit explained in *Nguyen v. Endologix*, it is not "plausible" to argue that defendants would "promise the market that the FDA would approve [the product] if defendants knew the FDA would eventually figure out that [the product] could not be approved," as such a theory depended on "the supposition that defendants would rather keep the stock price high for a time and then face the inevitable fallout." 962 F.3d at 415; FibroGen Mot. at 21-22. In response, Plaintiffs briefly and unconvincingly argue that *Endologix* "is inapplicable" because of different disclosure timing and less "problematic" data. Opp. at 34.

Given this Court's recent opinion in *Carr v. Zosano Pharma Corp.*, a sense of déjà vu would not be surprising:

> Plaintiffs' feeble attempt to distinguish this case from *Endologix* fails to address the latter's key conclusion: that allegations that company executives "would rather keep [a] stock price high for a time and then face the inevitable fallout" when their product fails to win regulatory approval on a certain timeline, without themselves seeking "to profit from this scheme in the interim," have scant "basis in logic or common experience." Consequently, allegations like these are implausible as a matter of law and cannot survive a motion to dismiss.

No. 20-CV-07625-EMC, 2021 WL 3913509, at *10 (N.D. Cal. Sept. 1, 2021) (citations omitted) (quoting *Endologix*, 962 F.3d at 407-08, 415).

C. The Complaint Does Not Adequately Allege a Controlling Person Claim Against Dr. Yu

Because Plaintiffs fail to state a claim under Section 10(b) in Count I, Plaintiffs' claim under Section 20(a) fails too. *In re Rigel Pharms., Inc. Sec. Litig.*, 697 F.3d 869, 886 (9th Cir. 2012).

III. CONCLUSION

For the foregoing reasons, for the reasons set forth in FibroGen's Reply (Dkt. 115), and because no conceivable amendment could cure these defects, Dr. Yu asks the Court to grant her motion to dismiss the CAC without leave to amend.

Dated: April 8, 2022

PILLSBURY WINTHROP SHAW PITTMAN LLP
WEI GROUP LLP

/s/ Bruce A. Ericson
Bruce A. Ericson
Attorneys for Defendant
K. Peony Yu, M.D.